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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,251	04/29/2005	Jan Peter Sternby	05049.0002	7073

22852 7590 04/25/2008

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
04/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,251	STERNBY, JAN PETER	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,15 and 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1, 6, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant sets forth that the whole body clearance ratio is a dimensionless positive numeral smaller than one. However, Applicant does not point to where in the specification such a definition of the clearance ratio may be found, and the Examiner can find no such definition of the clearance ratio anywhere in the specification. Accordingly, the definition is considered by the Examiner to be new matter.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-10, 12, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/55166 to Sternby.

In the specification and figures, Sternby discloses the method substantially as claimed by applicant. With regard to claim 1, Sternby discloses a method of estimating the efficiency of a dialysis treatment that comprises the steps of determining the effective clearance of the dialyser (see p 22, lines 10-20) as well as determining the whole body clearance (see p 10, lines 17-30) in calculating dialysis efficiency. Sternby does not specifically teach that the whole body clearance ratio comprises a "dimensionless positive numeral smaller than one." However, the limitation is not a positively recited method step, and the claimed method provides no way to ensure that the calculated clearance ratio falls within the value set forth by applicant. Accordingly, it is the position of the Examiner that the method suggested by Sternby is capable of generating a clearance ratio within the values set forth by applicant, thereby meeting the limitations of the claims.

With regard to claims 2-4, Sternby discloses a that the prior art uses a method of determining dialyzer clearance comprising the steps of measuring a blood urea concentration immediately at the end of treatment (which is interpreted by the examiner to be within the "approximately" one minute time frame), as well as 30-60 minutes after treatment, which is interpreted by the examiner to encompass applicant's claimed "no earlier than…one half hour after the end of treatment" (see p 10).

With regard to claim 5, Sternby discloses the steps of taking a urea measurement at time zero, taking several other urea measurements after a 60 minute waiting period, deriving a starting urea concentration m_0 based on the measured values,

and then dividing starting urea concentration m_0 by the measured blood concentration C_b (see p 17-19).

With regard to claims 6-8, Sternby discloses the steps of using a removal rate slope to determine whole body clearance or total urea removal (see p19, paragraphs 2-4). Sternby further discloses the use of the slope of K/V, based on the logarithm of the urea concentration (which is determined from the removal rate) to determine parameters relating to treatment efficiency, or whole body clearance (see p 16-17).

With regard to claims 9-10 and 16, Sternby discloses that these operations may be carried out on a standard hemodialysis system that is capable of measuring urea concentration on the blood side (Cb) or the dialysate side (Cd) of the device (see p 6-9) and is capable of estimating a whole body clearance ratio as claimed by applicant.

With regard to claims 12 and 14, Sternby discloses that the dialysis apparatus and urea monitor are controlled by computer 17. Since computer 17 operates the in the method claimed by applicant, the computer necessarily comprises the method claimed by applicant encoded on a computer readable medium so that the computer can execute the commands of the disclosed method. Therefore, the Sternby disclosure meets the limitations of the claims.

4. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/55166 to Sternby in view of US 6,284,141 to Shaldon.

In the specification and figures, Sternby discloses the method substantially as claimed by applicant, including the steps of performing dialysis under a first set of

conditions and analyzing that set of conditions to determine a particular result, which is affected by the operating parameters of the dialysis procedure. Sternby does not specifically disclose the step of performing dialysis again under a second set of conditions. However, Shaldon discloses a method of performing a blood treatment procedure under a first set of efficiency conditions and calculating efficiency while performing the operation. Once the first operation is finished, the method comprises the steps of performing the blood treatment procedure under a second set of conditions if necessary. This allows for two sessions of varying intensity to increase patient comfort (see Shaldon columns 1-4). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to use the calculations and method disclosed by Sternby to create and perform two discrete treatment sessions as disclosed by Shaldon in order to provide sessions of differing efficiency, increasing patient comfort, as taught by Shaldon.

Response to Arguments

5. Applicant's amendment and arguments filed 26 February 2008 have been entered and fully considered.

6. Applicant's arguments with regard to the 35 USC 102 rejection over Sternby have been fully considered and are persuasive. The rejections over Sternby as to the amended claims have been withdrawn. However, a new grounds of rejection is presented in view of Sternby (see rejection above).

7. Applicant's arguments with regard to the 35 USC 103 rejections over Sternby have been fully considered but they are not persuasive.

8. Applicant's argues that the Sternby reference measures treatment efficiency in relation to a patient's size in contrast to Applicant's claimed theoretical treatment efficiency. However, the Applicant does not actually claim the steps of determining the whole body clearance ratio *based on* or using the values of the potential cleaning capacity. Applicant's claim language merely relates whole body clearance to the cleaning capacity without actually using the values of the cleaning capacity to generate the clearance ratio. Accordingly, Sternby suggests the calculation of clearance ratio as claimed by Applicant.

9. Applicant further argues that Sternby provides only a conceptual explanation of the whole body clearance and alleges that the equations set forth in Sternby cannot be used to calculate a whole body clearance ratio. Applicant argues that one of the values in the equations used by Sternby may not be measured in the body. However, the arguments of counsel cannot take the place of factually supported evidence. See MPEP § 2145. In the instant case, Sternby discloses that the whole body clearance ratio, K, may be calculated from the disclosed variables, and does not disclose that those variables are unattainable. As such, it is the position of the Examiner that Sternby does, in fact, calculate a clearance ratio K.

10. Applicant argues that the instantly claimed clearance ratio cannot be increased by prolonging the treatment. However, applicant has not set forth in the claim language

that the calculated clearance ratio is tied to the potential cleaning capacity rather than other variables as disclosed by Sternby.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner
Art Unit 3761
23 April 2008